

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A clinical comparison between oral irrigation with Echinacea extract as mouthwash and chlorhexidine (0.12%) in chronic periodontitis patients.

Protocol summary

Study aim

goal: Comparison of the clinical effects of oral irrigation with Echinacea extract and Chlorhexidine as mouthwash on patients with chronic periodontitis.

Design

This is a double-blind controlled clinical trial study with 3 parallel groups using 3 different solutions.

Settings and conduct

Patients will be instructed to rinse for 30 seconds with 10 ml of undiluted mouth rinse once a day at night, for 28 days and to refrain from eating or drinking for 1 hour afterwards. Bass method will be taught to all patients. Also they will be instructed not to use any other dental hygiene products during the study period. Information gathering: The following procedure will be carried out for all patients, 1. Measuring Pocket depth 2. Bleeding index 3. Plaque index 4. Gingival index These clinical parameters will be measured before scaling and root planning and four weeks later at the follow-up session. Clinical examination and data gathering will be performed by a single practitioner who is blind to the groups. Complete scaling and root planning by cavitron and curette will be done for all the patients after the first measurements.

Participants/Inclusion and exclusion criteria

30 patients attending to the Department of Periodontology with chronic periodontitis. Inclusion criteria: 1-Presence of minimum of 22 teeth. 2-Moderate or severe chronic periodontitis. Exclusion criteria: 1- Patients with history of adverse reaction to chlorhexidine. 2-Antibiotic therapy during last 2 months. 3-Periodontal treatment during last 6 months. 4-Diabetes. 5-Pregnancy. 6-Lactation. 7-Tooth brushing more than 4 time. 8-Smoking

Intervention groups

Echinacea mouthwash will be given to the first group, CChlorhexidine will be given to the second group, and distilled water will be given to the third group.

Main outcome variables

Pocket depth Bleeding index Plaque index Gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044525N1**

Registration date: **2019-09-14, 1398/06/23**

Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **0**

Registration date

2019-09-14, 1398/06/23

Registrant information

Name

Mohammad sadegh Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3646 6378

Email address

karamims@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-13, 1398/05/22

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical comparison between oral irrigation with Echinacea extract as mouthwash and chlorhexidine (0.12%) in chronic periodontitis patients.

Public title

Comparison between oral irrigation with Echinacea mouthwash and chlorhexidine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of minimum of 22 teeth. Moderate or severe chronic periodontitis.

Exclusion criteria:

Patients with history of adverse reaction to chlorhexidine. Antibiotic therapy during last 2 months. Periodontal treatment during last 6 months. Diabetes. Pregnancy. Lactation. Tooth brushing more than 4 time per day. Smoking

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **180**

1. Measuring Pocket depth. 2. Bleeding index. 3. Plaque index. 4. Gingival index

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to groups a randomly by a person who is unaware to the stud by using the random numbers system.

Blinding (investigator's opinion)

Double blinded

Blinding description

same bottle will be use for all mouthwashes and a small color tag will be attach to botom of bottle. the bottle will be randomly given to patient by a third person who is blind to study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

In front of No 58 , Daneshvaran St, Choghah St,

City

Shiraz

Province

Fars

Postal code

7194786554

Approval date

2019-08-11, 1398/05/20

Ethics committee reference number

IR.SUMS.DENTAL.REC.1398.59

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

1. Measuring Pocket depth (PD) .

Timepoint

At base line and after 28 day

Method of measurement

William probe

2

Description

.2. Bleeding index (BI)

Timepoint

At base line and after 28 day

Method of measurement

Lenox method by probe

3

Description

3. Plaque index (PI).

Timepoint

At base line and after 28 day

Method of measurement

modified O'Leary method by disclosing agents

4**Description**

4. Gingival index (GI)

Timepoint

At base line and after 28 day

Method of measurement

Loe and Sillness method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Echinacea mouthwash (extract will be purchase from Zarband company and will be diluted with water to achieve .01% phenol as active compartment) will be given to the Intervention group.

Category

Treatment - Drugs

2**Description**

Control group: chlorhexidine will be given to the positive control group

Category

Treatment - Drugs

3**Description**

Control group: distilled water will be given to the negative control group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Periodontal department of Shiraz University of Medical Sciences dental school

Full name of responsible person

Hoda Sadat Banihashemi

Street address

Dental school,Ghas o dasht St .Shiraz.Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

انديشه تدبير

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Dental school,Ghas o dasht St .Shiraz.Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Sadegh Karami

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Sadegh Karami

Position

Student

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available